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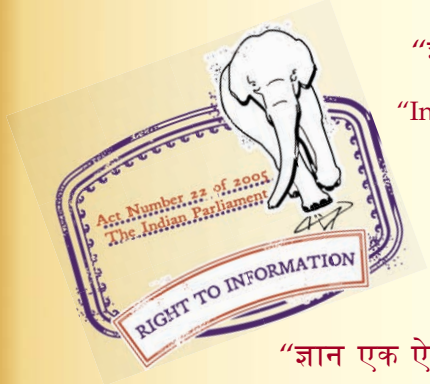
IS 7379 (1987): Clamps, Patent Ductus, Potts' Pattern, Straight and Angular [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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"Knowledge is such a treasure which cannot be stolen"

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Indian Standard

(Reaffirmed 2005)

SPECIFICATION FOR CLAMPS, PATENT DUCTUS, POTTS' PATTERN, STRAIGHT AND ANGULAR

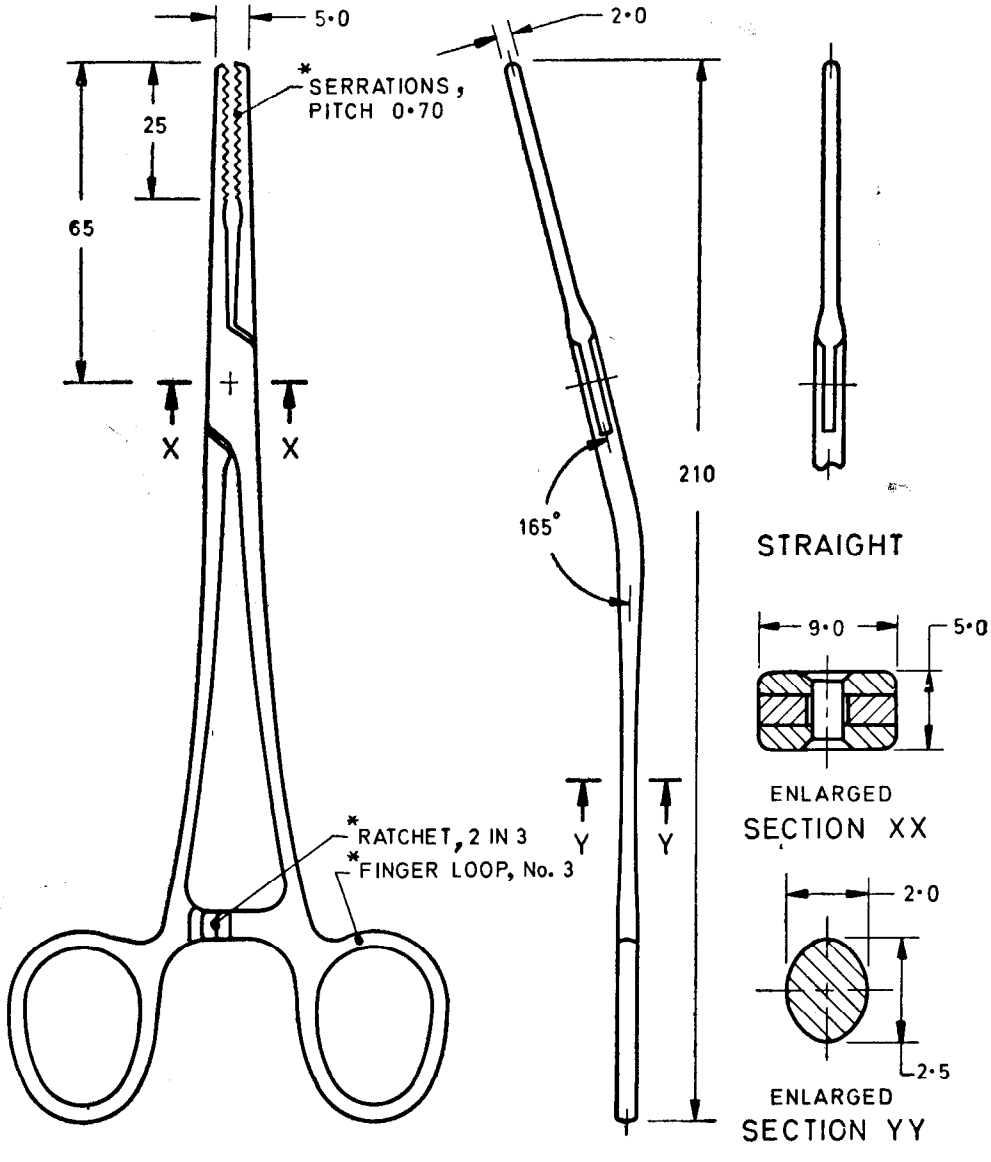
(First Revision)

Thoracic and Cardiovascular Surgery Instruments Sectional Committee, CPDC 28 [Ref : Doc : CPDC 28 (2049)]

1. Scope — Specifies requirements and tests for Potts' pattern, straight and angular patent ductus clamps used in cardiac surgery.

2. Material — Stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS : 6603-1972 'Specification for stainless steel bars and flats'.

3. Shape and Dimensions — As shown in Fig. 1.



*See IS : 3642-1978 'General requirements for surgical instruments (*first revision*).

All dimensions in millimetres.

FIG. 1 CLAMPS, PATENT DUCTUS, POTTS' PATTERN, STRAIGHT AND ANGULAR

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3.1 Tolerances on linear dimensions shall be in accordance with the following:

a) ±0·05 mm on dimensions up to 2·0 mm.

b) ±0·1 mm on dimensions above 2·0 mm and up to 5·0 mm,

c) ±0·2 mm on dimensions above 5·0 mm and up to 20·0 mm,

d) ±0·5 mm on dimensions above 20·0 mm and up to 50·0 mm,

e) ±1·0 mm on dimensions above 50·0 mm and up to 100·0 mm, and

f) ±2·0 mm on dimensions above 100·0 mm.

3.1.1 Tolerance on angular dimension shall be ± 2°.

3.1.2 The two halves of the instrument shall, however, not differ in any dimension and shall match with each other perfectly.

4. Mass — 30 to 50 g.

5. Heat Treatment — The instruments shall be uniformly hardened and tempered to a hardness of 400 to 460 HV, when tested in accordance with IS : 1501 (Part 1)-1984 'Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (*second revision*)'.

5.1 Mating surfaces on the same instrument, such as opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

6. Workmanship

6.1 The opening and closing of the jaws shall be smooth and jerk free.

6.2 The joint shall conform to the relevant requirements of **6** of IS : 3642-1978 'General requirements for surgical instruments (*first revision*)'.

6.3 The serrations on the jaws shall be transverse with non-truncated 60° profile and shall conform to the relevant requirements of Section 1 of IS : 3642-1978 except that the test for engagement of the jaws shall be as in **8.1**.

6.4 The ratchet teeth shall be in accordance with Section 3 of IS : 3642-1978.

6.5 The finger loops shall be in accordance with the relevant requirements of Section 5 of IS : 3642-1978.

6.6 There shall be no sharp edges.

7. Surface Condition

7.1 *General* — All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be supplied free from residual scales, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by inspection using normal vision (corrected, if necessary).

7.2 *Surface Finish* — The surface finish shall be one of, or a combination of, the following:

a) Mirror polished;

b) Reflection-reducing, for example satin finish, matt black finish; and

c) An applied surface coating, for example for insulation purposes.

Note — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing, and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. Tne mirror finish should be effected by an appropriate procedure, such as polishing, brushing, electropolishing, and mirror buffing.

7.3 *Passivation and Final Treatment* — The instruments shall be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (*v/v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

Note — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

8. Tests

8.1 *Test for Engagement of Jaws* — When the first ratchet is engaged, the serrations shall approximate to a gap of 1 mm at the extreme end of the tip. The serrations shall become parallel and ready for engagement when the second ratchet is engaged. On engaging the third ratchet, all serrations shall engage simultaneously along the entire length. The serrations shall engage perfectly and truly.

8.1.1 The load required to close the clamps on the first step of the ratchet shall be 2·5 N (250 gf approximately). For the second step, the load shall be 5 N (500 gf approximately) and for the third step 7·5 N (750 gf approximately).

8 2 *Flexibility Test* — Each arm of the clamps shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be deflected by 15 mm in the same plane as that of the finger loop. The arm shall not take a permanent set or break.

8.3 *Gripping Test* — A piece of fresh goat or pig aorta shall be placed between the jaws of the instrument. The instrument shall then be closed to the last ratchet position and kept under this strain for 3 hours at a temperature of 25 ± 2°C. After or during this test, no distortion, cracks or any other permanent deformation of the instrument shall be visible. The aorta shall not get crushed, pierced or damaged.

8.4 *Drop Test* — The instrument shall be dropped from a height of 150 cm on a concrete floor 5 times and shall then be examined visually. There shall be no damage or distortion or malfunctioning of the instrument. After this test, the clamps shall again satisfy the requirements of flexibility test.

8.5 *Corrosion Resistance Test* — The instruments shall be tested in accordance with IS : 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. They shall show no sign of corrosion after the test.

9. Marking and Packing

9.1 The instrument shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel' or the letters 'ss'; and the country of manufacture.

9.2 Each instrument shall be wrapped in a suitable cushioning material like folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

9.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

9.3 The packages shall be marked with the name and shape of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel'; and the country of manufacture.

9.4 *Certification Marking* — Details available with the Bureau of Indian Standards.

10. Sampling — The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Appendix A.

APPENDIX A

(*Clause* 10)

SAMPLING OF CLAMPS, PATENT DUCTUS, POTTS' PATTERN

A-1. Lot — In any consignment, all the instruments of same shape, produced from identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2. The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

(*Clauses* A-2, A-3.1 *and* A-3.2)

Lot Size	Sample Size	Sub-Sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS : 4905-1968 'Methods for random sampling' may be followed.

A-3. Number of Tests and Criteria for Conformity

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship, and surface condition (visual), and tested for mass and engagement of jaws. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness, flexibility, gripping, drop and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

EXPLANATORY NOTE

This standard was first issued in 1974. In this revision, tolerances on various dimensions have been specified, a recommended sampling plan has been added and the clauses on surface condition have been modified besides incorporating certain other modifications.

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